



IN THE UNITED STATES PATENT & TRADEMARKS OFFICE

ART UNIT: 1614
EXAMINER: UNKNOWN
APPLICANT: Fikstad et al.
SERIAL NO.: 10/764,016
FILED: 1/23/2004
CONFRM. NO.: 8956
FOR: PHARMACUETICAL COMPOSITIONS
WITH SYNCHRONIZED SOLUBILIZER
RELEASE

CERTIFICATE OF MAILING
UNDER 37 C.F.R. § 1.8

DATE OF DEPOSIT: 08/26/2004

I hereby certify that this paper or fee (along with any paper or fee referred to as being attached or enclosed) is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Denise Dyer
Denise Dyer

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

Please find, pursuant to 37 C.F.R. § 1.98(a)(1), the enclosed Form PTO-1449 which contains a list of all patents, publications, or other items that have come to the attention of one or more of the individuals designated in 37 C.F.R. § 1.56(c). Applicant respectfully submits that this Information Disclosure Statement is filed pursuant to:

☒ 37 C.F.R. § 1.97 (b)(1) or (3), within three months of the filing date of the application, or before a first office action on the merits, whichever occurs last;

☐ 37 C.F.R. § 1.97 (c), after a first office action on the merits, but before a Final Office Action or a Notice of Allowance, whichever occurs first, and is accompanied by either 1) a statement in accordance with 37 C.F.R. § 1.97(e), or 2) the fee set forth in § 1.17(p); or

☐ 37 C.F.R. § 1.97 (d), after a Final Office Action or Notice of Allowance, whichever occurs first, but on or before payment of the issue fee, and is accompanied by both 1) a statement in accordance with 37 C.F.R. § 1.97(e), and 2) the fee set forth in § 1.17(p).

While no representation is made that any of these references may be "prior art" within the meaning of that term in accordance with 35 U.S.C. §§ 102 or 103, the enclosed list of references is disclosed so as to comply with the duty of disclosure set forth in 37 C.F.R. § 1.56.

Moreover, while no representation is made that a specific search of office files or patent office records has been conducted or that no better art exists, the undersigned attorney of record believes that the references listed, together with any other references which may have been previously submitted or listed, are the closest to the claimed invention (taken in its entirety) of which the undersigned is presently

aware, and no art which is closer to the claimed invention (taken in its entirety) has been knowingly withheld.

☐ A legible copy of each listed U.S. Patent or publication (or relevant portion thereof) which was not previously submitted to, or cited by, the Patent Office is enclosed pursuant to 37 C.F.R. §§ 1.97 and 1.98.

☒ A legible copy of each of the listed non-patent literature and foreign documents or their relevant portions is enclosed.

☐ Copies of cited U.S. patents and/or publications are **NOT** enclosed pursuant to the Official Gazette Notice, dated Aug. 5, 2003, waiving the requirement of 37 C.F.R. § 1.98(a)(2)(i).

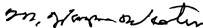
☐ Copies of the references listed in the accompanying Form PTO-1449 are **NOT** enclosed because, under 37 C.F.R. § 1.98(d), they were previously cited by or submitted to the Office in application number _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

For all listed references that are not either in the English language, or accompanied by a translation into English, a concise explanation of relevance as required under 37 C.F.R. § 1.98(a)(3) is enclosed attached to each.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or to credit any overpayment to Deposit Account No. 20-0100.


Dated this 26 day of August, 2004.


Respectfully submitted,



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MWW/DWO/dd
Enclosure

	PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 23625.CON	SERIAL NO. 10/764,016
	ST OF PRIOR ART CITED BY APPLICANT			
	APPLICANT Fikstad et al.		FILING DATE 01/23/2004	GROUP 1614

U.S. PATENT DOCUMENTS

EXAMINER INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1					
	A2					
	A3					
	A4					
	A5					
	A6					
	A7					
	A8					
	A9					

FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	A10					
	A11					
	A12					

OTHER PRIOR ART (Including Author, Title, Pertinent Pages, Etc.)

	A13	LANGER, "New Methods of Drug Delivery," <u>Science</u> (1990) 249: 1527-1533				
	A14	SAUDEK <i>et al.</i> , "A preliminary trial of the programmable implantable medication system for insulin delivery," <u>N. Engl. J. Med.</u> (1989) 321: 574-579				
	A15	SEFTON "Implantable pumps," (1987) <u>CRC Crit. Rev Biomed. Eng.</u> 14 (3):201-240				
	A16	TREAT <i>et al.</i> , in "Liposomes in the Therapy of Infectious Disease and Cancer," Lopez-Berestein and Fidler (eds.), Liss, New York (1989) 353-365				
EXAMINER				DATE CONSIDERED		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.